

105TH CONGRESS
1ST SESSION

H. R. 2469

To amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regulation of food ingredients, nutrient content claims, and health claims, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 11, 1997

Mr. WHITFIELD (for himself, Mr. TOWNS, Mr. KLUG, Mr. HALL of Texas, Mr. GREENWOOD, Mr. MANTON, Mr. BURR of North Carolina, Ms. MCCARTHY of Missouri, Mr. BARTON of Texas, Mr. COBURN, Mr. UPTON, Mr. DEAL of Georgia, Mr. BILIRAKIS, Mr. ENGEL, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regulation of food ingredients, nutrient content claims, and health claims, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CON-**
4 **TENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Food and Nutrition Information Reform Act”.

(b) REFERENCE.—Unless otherwise stated, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents is as follows:

Sec. 1. Short title; reference; table of contents.

TITLE I—IMPROVING THE REGULATION AND LABELING OF FOOD

Sec. 101. Flexibility for regulations regarding claims.

Sec. 102. Petitions for claims.

Sec. 103. Health claims for food products.

Sec. 104. Nutrient content claims.

Sec. 105. Referral statements.

Sec. 106. Disclosure of irradiation.

Sec. 107. Margarine.

TITLE II—EFFECTIVE DATE

Sec. 201. Effective date.

TITLE I—IMPROVING THE REGULATION AND LABELING OF FOOD

SEC. 101. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended by adding at the end the following:

“(D) Proposed regulations under this paragraph may be made effective upon publication at the discretion of the Secretary, notwithstanding the provisions of 5 U.S.C. 553, pending consideration of public comment and publication

1 of a final regulation. Such regulations shall be effective
2 for a period not to exceed 270 days and shall be deemed
3 final agency action for purposes of judicial review.”.

4 **SEC. 102. PETITIONS FOR CLAIMS.**

5 Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended
6 as follows:

7 (1) By adding after the second sentence the fol-
8 lowing: “If the Secretary does not act within such
9 100 days, the petition shall be deemed to be de-
10 nied.”.

11 (2) In the fourth sentence of subparagraph
12 (A)(i) (as amended by paragraph (1)) by inserting
13 immediately before the comma the following: “or the
14 petition is deemed to be denied”.

15 (3) Subparagraph (A)(i) is amended by adding
16 at the end the following: “If the Secretary does not
17 act within such 90 days, the petition shall be deemed
18 to be denied. If the Secretary issues a proposed reg-
19 ulation, the rulemaking shall be completed within
20 540 days of the date the petition is received by the
21 Secretary and the proposed regulation shall be con-
22 sidered a final regulation if the Secretary does not
23 complete the rulemaking within such 540 days.”.

1 **SEC. 103. HEALTH CLAIMS FOR FOOD PRODUCTS.**

2 Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended
3 by adding at the end thereof the following:

4 “(C) Notwithstanding the provisions of clauses (A)(i)
5 and (B), a claim of the type described in subparagraph
6 (1)(B) which is not authorized by the Secretary in a regu-
7 lation promulgated in accordance with clause (B) shall be
8 authorized and may be made with respect to a food if—

9 “(i) a scientific body of the United States Gov-
10 ernment with official responsibility for public health
11 protection or research directly relating to human nu-
12 trition (such as the National Institutes of Health,
13 the Centers for Disease Control and Prevention, or
14 the National Academy of Sciences or subdivisions of
15 such scientific body) has published an authoritative
16 statement, which is currently in effect, about the re-
17 lationship between a nutrient and a disease or
18 health-related condition to which the claim refers;

19 “(ii) a person has submitted to the Secretary,
20 at least 120 days before the first introduction into
21 interstate commerce of the food with a label contain-
22 ing the claim, a notice of the claim, including a con-
23 cise description of the basis upon which such person
24 relied for determining that the requirements of sub-
25 clause (i) have been satisfied;

1 “(iii) the claim and the food for which the claim
2 is made are in compliance with clause (A)(ii) and
3 are otherwise in compliance with paragraph (a) and
4 section 201(n); and

5 “(iv) the claim is stated in a manner so that
6 the claim is an accurate representation of the au-
7 thoritative statement referred to in clause (i) and so
8 that the claim enables the public to comprehend the
9 information provided in the claim and to understand
10 the relative significance of such information in the
11 context of a total daily diet.

12 For purposes of this clause, a statement shall be regarded
13 as an authoritative statement of such a scientific body de-
14 scribed in subclause (i) only if the statement is published
15 by the scientific body and shall not include a statement
16 of an employee of the scientific body made in the individ-
17 ual capacity of the employee.

18 “(D) A claim submitted under the requirements of
19 clause (C) may be made until—

20 “(i) such time as the Secretary issues a regula-
21 tion under the standard in clause (B) (I) prohibiting
22 or modifying the claim and the regulation has be-
23 come effective, or (II) finding that the requirements
24 of clause (C) have not been met; or

1 “(ii) a district court of the United States in an
2 enforcement proceeding under chapter III has deter-
3 mined that the requirements of clause (C) have not
4 been met.”.

5 **SEC. 104. NUTRIENT CONTENT CLAIMS.**

6 Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended
7 by adding at the end the following:

8 “(G) A claim of the type described in subparagraph
9 (1)(A) for a nutrient, for which the Secretary has not pro-
10 mulgated a regulation under clause (A)(i), shall be author-
11 ized and may be made with respect to a food if—

12 “(i) a scientific body of the United States Gov-
13 ernment with official responsibility for public health
14 protection or research directly relating to human nu-
15 trition (such as the National Institutes of Health,
16 the Centers for Disease Control and Prevention, or
17 the National Academy of Sciences or subdivisions of
18 such scientific body) has published an authoritative
19 statement, which is currently in effect, which sets
20 forth a basis for such claim;

21 “(ii) a person has submitted to the Secretary,
22 at least 120 days before the first introduction into
23 interstate commerce of the food with a label contain-
24 ing the claim, a notice of the claim, including a con-
25 cise description of the basis upon which such person

1 relied for determining that the requirements of sub-
2 clause (i) have been satisfied;

3 “(iii) the claim and the food for which the claim
4 is made are in compliance with clauses (A) and (B),
5 and are otherwise in compliance with paragraph (a)
6 and section 201(n); and

7 “(iv) the claim is stated in a manner so that
8 the claim is an accurate representation of the au-
9 thoritative statement referred to in subclause (i) and
10 so that the claim enables the public to comprehend
11 the information provided in the claim and to under-
12 stand the relative significance of such information in
13 the context of a total daily diet.

14 For purposes of this clause, a statement shall be regarded
15 as an authoritative statement of such a scientific body de-
16 scribed in subclause (i) only if the statement is published
17 by the scientific body and shall not include a statement
18 of an employee of the scientific body made in the individ-
19 ual capacity of the employee.

20 “(H) A claim submitted under the requirements of
21 clause (G) may be made until—

22 “(i) such time as the Secretary issues a regula-
23 tion (I) prohibiting or modifying the claim and the
24 regulation has become effective, or (II) finding that

1 the requirements of clause (G) have not been met;
2 or

3 “(ii) a district court of the United States in an
4 enforcement proceeding under chapter III has deter-
5 mined that the requirements of clause (G) have not
6 been met.”.

7 **SEC. 105. REFERRAL STATEMENTS.**

8 Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is
9 amended to read as follows:

10 “(B) If a claim described in subparagraph (1)(A) is
11 made with respect to a nutrient in a food, and the Sec-
12 retary makes a determination that the food contains a nu-
13 trient at a level that increases to persons in the general
14 population the risk of a disease or health-related condition
15 that is diet related, then the label or labeling of such food
16 shall contain, prominently and in immediate proximity to
17 such claim, the following statement: ‘See nutrition infor-
18 mation for ____ content.’ The blank shall identify the nu-
19 trient associated with the increased disease or health-relat-
20 ed condition risk. In making the determination described
21 in this clause, the Secretary shall take into account the
22 significance of the food in the total daily diet.”.

23 **SEC. 106. DISCLOSURE OF IRRADIATION.**

24 Chapter IV (21 U.S.C. 341 et seq.) is amended by
25 inserting after section 403B the following:

1 “DISCLOSURE

2 “SEC. 403C. (a) No provision of section 403(a),
 3 201(n) or 409 shall be construed to require on the label
 4 or labeling of a food a separate radiation disclosure state-
 5 ment that is more prominent than the declaration of ingre-
 6 dients required by section 403(i)(2).

7 “(b) In this section, the term ‘radiation disclosure
 8 statement’ means a written statement that discloses that
 9 a food or a component of the food has been intentionally
 10 subject to radiation.”.

11 **SEC. 107. MARGARINE.**

12 (a) SECTION 301(m).—Paragraph (m) of section 301
 13 (21 U.S.C. 331) is amended by striking “section 407(b)
 14 or 407(c)” and inserting “section 407”.

15 (b) SECTION 407.—Section 407 (21 U.S.C. 347) is
 16 amended to read as follows:

17 “OLEOMARGARINE AND MARGARINE

18 “SEC. 407. No person shall sell, or offer for sale, ole-
 19 omargarine or colored margarine unless the principal dis-
 20 play panel of such oleomargarine or margarine bears as
 21 one of its principal features the word “oleomargarine” or
 22 “margarine” which is in—

23 “(1) bold type on such panel;

24 “(2) a size reasonably related to the most
 25 prominent printed matter (but no less than one-half
 26 the point size of such matter); and

1 “(3) lines generally parallel to the base on
2 which the package rests as it is designed to be dis-
3 played.”.

4 (c) ACT OF MARCH 16, 1950.—Sections 3(a) and 6
5 of the Act of March 16, 1950 (21 U.S.C. 347a, 347b),
6 are repealed.

7 **TITLE II—EFFECTIVE DATE**

8 **SEC. 201. EFFECTIVE DATE.**

9 The amendments made by this Act shall take effect
10 on the date of the enactment of this Act. The Secretary
11 of Health and Human Services shall not enforce any regu-
12 lation that is inconsistent with the amendment made by
13 section 101 after the date of the enactment of this Act.

